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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,195	08/03/2001	Rosely M. Zancope-Oliveira	65798	3262

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127 PEACHTREE STREET N E
ATLANTA, GA 30303-1811

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/19/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/674,195

Applicant(s)
Zancopé-Oliveira et al

Examiner
Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above, claim(s) 10-15, 21-30, and 34-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 16-20, and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 & 12 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-9, 16-20 and 31-33 in Paper No. 11 (received July 16, 2002) is acknowledged. The traversal is on the ground(s) that there exists a relationship between the DNA of Group I and the polypeptides of Group II such that any proper search of the art for examination of Group II will necessarily require a search of the literature inclusive of references pertinent for examination of Group I. This is not found persuasive because it is the Examiner's position that the search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. As shown by the MPEP manual of classification, DNA is classified in Group 536, subclass 23.1, while polypeptides are classified in Group 530, subclass 350. Clearly a patent search requires separate searches and is not coextensive. Furthermore, Applicant's are respectfully directed to *In re Duel* 34 USPQ2d 1210 (CAFC 1995), which clearly shows that a protein can be anticipated by a reference which discloses that protein, but it does not anticipate or render obvious the DNA encoding the protein.

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Consequently, claims 1-44 are pending in the instant application, of which claims 10-15, 21-30, and 34-44 are withdrawn from further consideration as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. Claims 1, 4-9, 16, 18-20, 31, and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1, 4-9, 16, 18-20, 31, and 33 recite isolated nucleic acids, vectors and host cells which are specific to *Histoplasma capsulatum* comprising SEQ ID NO: 1, or nucleic acids "substantially the same as SEQ ID NO: 1" and "fragments of SEQ ID NO: 1."

The written description of the specification is fully enabled for the full length SEQ ID NO: 1, however, the written description requirement is not met for "substantially the same as SEQ ID NO: 1 or fragments of SEQ ID NO: 1."

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants,

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and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 1 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by SEQ ID NO: 1 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Furthermore, Applicants recitation of "fragments of SEQ ID NO: 1" can be construed to include fragments as small as a single nucleotide. This combined with the recitation of "having" which is deemed to be equivalent to "comprising" encompasses every single DNA molecule isolated since the beginning of time. Traditional phrases such as "having" must be interpreted in light of the specification to determine whether open or closed claim language is intended. (See MPEP 2111.03). Transitional phrases such as "having" must be interpreted in light of the specification to determine whether open or closed claim language is intended. (See *Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) (The term "having" was interpreted as open terminology, allowing the inclusion of other components in addition to those recited). In view that Applicant's specification does not set forth

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of a definition for the term “having” the recitation of “having” is deemed to encompass open language.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

3. Claims 1, 4-5, 8-9, 16, 18, 20, 31 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of “substantially the same.” One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, at what point is the DNA molecule considered substantially the same (e.g., 99%, 90%, 70%, 40%, etc.)? Conversely at what point is the DNA molecule no longer substantially the same? Without a clear definition as to the metes and bounds of the term “substantially the same” one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-9, 16-20 and 31-33 are rejected under 35 U.S.C. 102(a) as being anticipated by Zancope-Oliveria *et al.*

The claims are directed to an isolated nucleic acid specific to *Histoplasma capsulatum* comprising, a nucleic acid comprising SEQ ID NO: 1 (which encodes the M antigen), complementary to SEQ ID NO: 1, substantially the same as SEQ ID NO: 1, and fragments of SEQ ID NO: 1, as well as vectors and host cells comprising the DNA sequences.

Zancope-Oliveria *et al* (IDS reference A13) disclose of the isolation and characterization of the M antigen of *Histoplasma capsulatum*. (See abstract).

In view that Zancope-Oliveria *et al* disclose of the isolation of the DNA encoding the M antigen of *Histoplasma capsulatum*, as well as its presence with a vector and host cell, the disclosure of Zancope-Oliveria *et al* is deemed to anticipate the claimed invention.

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5. Claims 1 and 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Stryer.

The claims are directed to an isolated nucleic acid specific to *Histoplasma capsulatum* comprising a nucleotide sequence as set forth in SEQ ID NO: 1 or a fragment of a nucleic acid sequence having a sequence as set forth in SEQ ID NO: 1.

Stryer (BIOCHEMISTRY 3rd edition, New York, 1988, page 72) disclose of the building blocks of DNA and shows the structure of Adenine, Guanine, Thymine and Cytosine. Each of these molecules is a “fragment” of the isolated nucleic acid sequence as set forth in SEQ ID NO: 1.

6. Claims 1, 4-9, 16, 18-20, 31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee *et al.*

The claims are directed to an isolated nucleic acid specific to *Histoplasma capsulatum* comprising, a nucleic acid comprising SEQ ID NO: 1, substantially the same as SEQ ID NO: 1, and fragments of SEQ ID NO: 1, as well as vectors and host cells comprising the DNA sequences.

Lee *et al* (US Patent Number 5,693,501) disclose of isolated nucleic acids specific to *Histoplasma capsulatum* as well as their presence in vectors and host cells. (See claims and column 6).

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In view that Lee *et al* disclose of isolated nucleic acids specific to *Histoplasma capsulatum* as well as vectors and host cells, the disclosure of Lee *et al* is deemed to be substantially the same as the claimed SEQ ID NO: 1. Furthermore, since the nucleic acid disclosed by Lee *et al* shares multiple nucleotides in common, the disclosure of Lee *et al* is also deemed to anticipate the claimed fragment language.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

June 18, 2003